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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,488	03/25/2008	Brett P. Monia	0295.03/PCT-US	7913

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
06/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,488	MONIA ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-10,14-20,25,29,31,34,41-43,47-53 and 58* is/are pending in the application.

4a) Of the above claim(s) *1, 8-10, 14-20, 25, 29, and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,41,43 and 47-49* is/are rejected.

7)☒ Claim(s) *42,50-53 and 58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed March 16, 2009.

Claim 34 has been amended.

Claims 1, 8-10, 14-20, 25, 29, 31, 34, 41-43, 47-53, and 58 are pending in the instant application.

This application contains claims 1, 8-10, 14-20, 25, 29, and 31 drawn to an invention nonelected with traverse in the reply filed on August 19, 2008. Additionally, this application contains nucleotides 562 to 648 and 659 to 688 of SEQ ID NO:1 and nucleotides 3722 to 3747 of SEQ ID NO:127 as recited in claim 34 drawn to an invention nonelected with traverse in the reply filed on August 19, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 34, 41-43, 47-53, and 58 and nucleotides 1194 to 1277 of SEQ ID NO:1 as recited in claim 34 have been examined on the merits.

Specification

Applicant's reference to priority in the first sentence of the specification is acknowledged. However, the reference should be updated to reflect applications for patents that are pending.

Double Patenting

In the previous Office Action mailed September 17, 2008, claims 34, 41-43, 47-53, and 58 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent No. 6,448,079. **This rejection is withdrawn** in view of Applicant's Amendment filed March 16, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite that the antisense compound does not comprise SEQ ID NO: 90, 91, and 92. It is noted that the antisense compound of US Patent No. 6,448,079 comprises SEQ ID NO:90, 91, and 92, and therefore, the rejection is obviated.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed September 17, 2008, claims 34 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,994,076 ('076). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed September 17, 2008.

Response to Arguments

In response to this rejection, Applicants argue that claim 34 has been amended and is directed to an antisense compound about 19 to about 23 nucleobases in length. Applicants argue that the '076 Patent discloses a primer that is a 26mer and therefore fails to disclose an antisense compound about 19 to about 23 nucleobases in length.

This argument has been fully considered, but is not found persuasive because the Examiner acknowledges that the '076 Patent discloses a primer that is a 26mer. The Examiner also acknowledges that claim 34 has been amended and is directed to an antisense compound about 19 to about 23 nucleobases in length. However, Applicant is reminded that during patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See MPEP § 2111-2116.01. Given its broadest reasonable interpretation, the Examiner has interpreted the 26mer primer disclosed by the 076 Patent to be about 23 nucleobases in length.

Therefore, claims 34 and 43 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,994,076.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed September 17, 2008, claims 34, 41, 43, and 47-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,994,076 ('076) in view of Skerra, A. (Nucleic Acids Research, 1992 Vol. 20:3551-3554).

This rejection is maintained for the reasons of record set forth in the previous Office Action mailed September 17, 2008.

Response to Arguments

In response to this rejection, Applicants argue that the primers disclosed by the

'076 Patent have no intended biological effect. Applicants argue that similarly, Skerra makes no mention of compounds with antisense activity or boasting any other biological effect intended for the oligonucleotides, beyond the use as primers. In this light, Applicants contend that the combination of the '076 Patent and Skerra fails to provide a person of ordinary skill in the art with any motivation to consider the field of antisense technology.

This argument has been fully considered, but is not found persuasive because the recitation of "antisense compound" in claim 34 is an intended use. Applicant is reminded that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the functionality of the claim(s).

In the instant case, the 26mer primer taught by the '076 Patent is 100% complementary to at least a 9-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1 of Applicant's invention. Furthermore, the 26mer primer is taught by the '076 Patent to be a specific antisense primer of p38α mitogen-activated protein kinase (see Table 1). Given this high degree of complementarity, the 26mer primer would be capable of targeting a nucleic acid molecule encoding a p38α mitogen-activated protein kinase as recited in Applicant's claimed invention. Therefore, a person of ordinary skill in the art would be motivated to consider the field of antisense technology and combine the teachings of the '076 Patent and Skerra.

Applicants next argue that the '076 Patent teaches 1375 primers. Applicants

contend that of 1375 primers, a person of ordinary skill in the art would not know which primer has antisense activity. Applicants argue that any focus by the person of ordinary skill in the art one of the 1375 primers would be utterly random.

This argument has been fully considered, but is not found persuasive because it is noted that the '076 Patent teaches 1375 primers. It is also acknowledged that one of the 1375 primers is partially identical to a nucleic acid molecule encoding a p38α mitogen-activated protein kinase. However, Applicant is reminded of the premise behind a 35 U.S.C. 103 rejection:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

In the instant case, the '076 Patent teaches SEQ ID NO:1090 is 100% complementary to at least a 9-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1 of Applicant's invention. Furthermore, the 26mer primer is disclosed by the '076 Patent to be a specific antisense primer of p38α mitogen-activated protein kinase (see Table 1). Given this high degree of complementarity, and given this disclosure, the 26mer primer would be capable of targeting a nucleic acid molecule encoding a p38α mitogen-activated protein kinase as recited in Applicant's claimed invention. Regardless of the fact that the '076 Patent teaches 1374 other primers that can be used in their invention, these other 1374 primers do not exhibit the required partial identity to a nucleic acid sequence as specified in Applicant's claims. Nor are the other 1374 primers disclosed as being p38α mitogen-activated protein kinase specific. Further, the

mere disclosure of SEQ ID NO:1090 by the '076 and the fact that SEQ ID NO:1090 is a specific antisense primer for a p38α mitogen-activated protein kinase would prompt one of ordinary skill in the art to use this 26mer primer as an antisense compound since it is targeted to an 8-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1 as claimed in Applicant's invention.

Applicants next argue that the compounds in the claimed invention are the results of a focused and extensive selection process and therefore, the '076 Patent and Skerra fail individually and in combination to provide the person of ordinary skill in the art with any motivation to design a nucleic acid molecule encoding a p38α mitogen-activated protein kinase with antisense activity.

This argument has been fully considered but is not found persuasive because first, the Examiner appreciates that Applicants have used selective screening processes to generate the antisense compounds of their invention. However, the claims are drawn to:

> An antisense compound about 19 to about 23 nucleobases in length targeted to a nucleic acid molecule encoding a p38α mitogen-activated protein kinase, wherein said antisense compound is complementary to at least an 8-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1.

The '076 Patent teaches SEQ ID NO:1090, which is a p38α mitogen-activated protein kinase specific primer and is 100% complementary to at least a 9-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1 of Applicant's invention. Therefore, given this high degree of complementarity, the 26mer primer would be capable of targeting a nucleic acid molecule encoding a p38α mitogen-activated protein kinase as

recited in Applicant's claimed invention.

Second, Applicant is reminded that the claims are directed to an antisense compound. Applicant's arguments regarding the focused and extensive selection process used to screen oligonucleotide compounds to generate the antisense compound of Applicant's invention are irrelevant since the claims are not drawn to methods of screening or methods of selection.

In view of the foregoing, after consideration of all the evidence and facts, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

Conclusion

Claims 42, 50-53 and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 29 and 30 are considered to be free of the prior art since the prior art does not teach or fairly suggest an antisense compound about 19 to about 23 nucleobases in length targeted to a nucleic acid molecule encoding a p38α mitogen-activated protein kinase, wherein said antisense compound is complementary to at least an 8-nucleobase portion of nucleotides 1194 to 1277 of SEQ ID NO:1, wherein the antisense compound is a chimeric oligonucleotide; wherein the antisense compound comprises a 2'-O-

methyoxyethyl moiety; wherein the antisense compound comprises a 5'-methyl cytosine; and wherein the antisense compound is a pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Terra Cotta Gibbs/
May 30, 2009

/Sean R McGarry/

Primary Examiner, Art Unit 1635